

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Chapter I

[EPA-HQ-OPPT-2013-0443; FRL-9395-3]

Hydrofluorosilicic Acid in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response

AGENCY: Environmental Protection Agency (EPA).

ACTION: Petition; reasons for Agency response.

SUMMARY: This document announces the availability of EPA's response to a petition received by EPA under the Toxic Substances Control Act (TSCA). The TSCA section 21 petition, dated May 9, 2013, was submitted by American University students, alumni, and faculty. The petitioners requested EPA to take action to prohibit the use of hydrofluorosilicic acid (HFSA) as a water fluoridation agent. After careful consideration, EPA denied the TSCA section 21 petition for the reasons discussed in this document.

DATES: EPA's response to this TSCA section 21 petition was signed August 6, 2013.

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SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Operators and customers of public water systems may have particular interest in this action. This action also might be of interest to those persons who manufacture (including import) or process HFSA or other fluoridation agents.

B. How Can I Access Information About this Petition?

The docket for this TSCA section 21 petition, identified by docket identification (ID) number EPA-HQ-OPPT-2013-0443, is available at http://www.regulations.gov or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at http://www.epa.gov/dockets.

II. TSCA Section 21

A. What is a TSCA Section 21 Petition?

Under TSCA section 21 (15 U.S.C. 2620), any person can petition EPA to initiate a rulemaking proceeding for the issuance, amendment, or repeal of a rule under TSCA section 4, 6, or 8 or an order under TSCA section 5(e) or 6(b)(2). A TSCA section 21 petition must set forth the facts that are claimed to establish that it is necessary to take the

requested action. EPA must grant or deny the petition within 90 days of its filing. If EPA grants the petition, the Agency must promptly commence an appropriate proceeding. If EPA denies the petition, the Agency must publish its reasons for the denial in the **Federal Register**. 15 U.S.C. 2620(b)(3). A petitioner may commence a civil action in a U.S. district court to compel initiation of the requested rulemaking proceeding within 60 days of either a denial or the expiration of the 90-day period. 15 U.S.C. 2620(b)(4).

B. What Criteria Apply to a Decision on a TSCA Section 21 Petition?

Section 21(b)(1) of TSCA requires that the petition "set forth the facts which it is claimed establish that it is necessary" to issue the rule or order requested. 15 U.S.C. 2620(b)(1). Thus, TSCA section 21 implicitly incorporates the statutory standards that apply to the requested actions. In addition, TSCA section 21 establishes standards a court must use to decide whether to order EPA to initiate rulemaking in the event of a lawsuit filed by the petitioner after denial of a TSCA section 21 petition. 15 U.S.C. 2620(b)(4)(B). Accordingly, EPA has relied on the standards in TSCA section 21 and in the provision under which the action has been requested to evaluate this TSCA section 21 petition.

Of particular relevance here is the legal standard regarding TSCA section 6 rules. In order to promulgate a rule under TSCA section 6, the EPA Administrator must find that "there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture . . . presents or will present an unreasonable risk." 15 U.S.C. 2605(a). This finding cannot be made considering risk alone. Under TSCA section 6, a finding of "unreasonable risk" requires

the consideration of costs and benefits. Specifically, in promulgating any rule under TSCA section 6(a), the statute (15 U.S.C. 2605(c)(1)) requires that the EPA Administrator consider:

- The effects of such chemical substance or mixture on health and the magnitude of the exposure of human beings to such chemical substance or mixture.
- The effects of such chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such chemical substance or mixture.
- The benefits of such chemical substance or mixture for various uses and the availability of substitutes for such uses.
- The reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

Furthermore, the control measure adopted is to be the "least burdensome requirement" that adequately protects against the unreasonable risk. 15 U.S.C. 2605(a).

In addition, TSCA section 21(b)(4)(B) provides the standard for judicial review should EPA deny a request for rulemaking under TSCA section 6(a): "If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that ... there is a reasonable basis to conclude that the issuance of such a rule ... is necessary to protect health or the environment against an unreasonable risk of injury," the court shall order the EPA Administrator to initiate the requested action. 15 U.S.C. 2620(b)(4)(B).

Finally, TSCA section 9(b) directs EPA to take regulatory action on a chemical substance or mixture under other statutes administered by the Agency if the EPA Administrator determines that actions under those statutes could eliminate or reduce to a

sufficient extent the risks posed by the chemical substance or mixture. If this is the case, the regulation can be promulgated under TSCA only if the EPA determines that it is in the "public interest" to protect against that risk under TSCA rather than the alternative authority. 15 U.S.C. 2608(b).

III. Summary of the TSCA Section 21 Petition

A. What Action was Requested?

In the petition, dated May 9, 2013, American University students, alumni, and faculty seek to have EPA take action under TSCA section 6 to prohibit the use of HFSA as a water fluoridation agent (Ref. 1).

B. What Support Do the Petitioners Offer?

The petitioners claim that HFSA leads to the contamination of drinking water with arsenic, lead, and radionuclides. In addition, the petitioners claim that an existing alternative source of fluoride for water fluoridation, pharmaceutical grade sodium fluoride (NaF), would not contribute to drinking water levels of arsenic, lead, or radionuclides comparable to those in HFSA. The following is a summary of major claims by the petitioners:

1. Arsenic. Petitioners claim that an alternate source of fluoride, pharmaceutical grade NaF, delivers at least 100-fold lower levels of arsenic than does HFSA when water authorities choose to adjust their water supply to contain about 0.7 milligram per liter (mg/L) of fluoride. The petitioners cite an analysis that purports to show that for typical levels of arsenic in HFSA and pharmaceutical grade NaF, use of pharmaceutical grade NaF as a fluoridation agent produces about 100-fold fewer lung and bladder cancer cases than HFSA (3.4 versus 320 cases) (Ref. 2). That analysis also purports to show that use

of typical pharmaceutical grade NaF, rather than HFSA (delivering an average level of arsenic as determined by National Sanitation Foundation (NSF) tests), results in over 500-fold fewer lung and bladder cancer cases (3.4 versus 1,800 cases). Based on this analysis, the petitioners assert that the net cost to the citizens of the United States of using HFSA is at least \$1,011 million (M) to \$6,191M more per year than using the pharmaceutical grade NaF (Ref. 2; see Tables 1-3, case 1 and case 4).

- 2. Lead. Petitioners claim that HFSA contains lead and that the use of HFSA results in leaching of lead from lead-containing water piping systems into water. The petitioners also claim that when chloramine is used in conjunction with silicofluorides (chemical substances composed of silicon and fluorine), such as HFSA, enhanced leaching of lead into water occurs (Refs. 3, 4, and 5). Petitioners further claim that when pharmaceutical grade NaF is used as the fluoridating agent, rather than HFSA, leaching of lead is greatly reduced or eliminated altogether. The petitioners assert children drinking water fluoridated with silicofluorides are at increased risk of having elevated blood lead levels (Refs. 6 and 7).
- 3. *Radionuclides*. Petitioners also expressed concerns about radionuclides impurities in HFSA and increased risk of cancer as a common concern for all radionuclides (Refs. 1 and 8).

IV. Disposition of TSCA Section 21 Petition

A. What is EPA's Response?

After careful consideration, EPA denied the TSCA section 21 petition primarily because EPA concluded that petitioners have not set forth sufficient facts to establish that HFSA presents or will present an unreasonable risk and that it is necessary to initiate a

TSCA section 6(a) rulemaking to protect adequately against such risk. A copy of the Agency's response, which consists of a letter to the petitioners, is available in the docket for this TSCA section 21 petition.

B. What is EPA's Reason for this Response?

For the purpose of making its decision, EPA evaluated the information presented or referenced in the petition as well as the Agency's authority and requirements under TSCA sections 6, 9, and 21. After careful consideration, EPA denied the TSCA section 21 petition because the evidence presented by the petitioners does not adequately support a conclusion that HFSA, when used as a fluoridation agent, presents or will present an unreasonable risk to health or the environment and that a TSCA section 6 rulemaking is necessary to protect adequately against such risk. More specifically:

1. Arsenic. EPA evaluated the cost-benefit analysis submitted by the petitioners and determined that the petitioners miscalculated net benefits for pharmaceutical grade NaF compared to HFSA. Specifically, it appears that the petitioners failed to convert their estimates of lifetime cancer risk to estimates of annual cancer risk for the purpose of calculating annual net benefits. This error alone results in a 70-fold overestimation of the number of annual cancer cases due to arsenic. That is, for the analysis in which the petitioners evaluate arsenic concentrations of 0.078 parts per billion (ppb) due to HFSA and 0.00084 ppb due to pharmaceutical grade NaF, the estimated numbers of cancer cases, when corrected, decrease from 320 to 4.6 per year for HFSA and from 3.4 to 0.05 per year for pharmaceutical grade NaF (Refs. 2 and 9). Similarly, for the analysis in which the petitioners evaluate an arsenic concentration of 0.43 ppb due to HFSA and 0.00084 due to pharmaceutical grade NaF, the estimated numbers of cancer cases, when

corrected, decrease from 1,800 to 25 per year for HFSA and from 3.4 to 0.05 per year for pharmaceutical grade NaF (Refs. 2 and 9). After making the correction (i.e., annualizing the lifetime cancer risk), and retaining all other assumptions of the petitioners analysis, the analysis actually indicates that the cost-benefit ratio is in favor of using HFSA over pharmaceutical grade NaF (-\$81M/year to -\$8M/year, respectively) rather than pharmaceutical grade NaF over HFSA (Ref. 9). As a result, the information submitted by petitioners does not support the petitioners' claim that there are net benefits in switching from HFSA to pharmaceutical grade NaF. Given that the petition is based upon the premise that the benefits of using pharmaceutical grade NaF as a fluoridation agent significantly exceed the costs relative to the use of HFSA as a fluoridation agent, EPA concludes that petitioners have not set forth sufficient facts to establish that HFSA presents or will present an unreasonable risk of injury to health or the environment with respect to arsenic or that it is necessary to initiate a TSCA section 6(a) rulemaking to protect adequately against such risk.

2. Lead. Petitioners assert that HFSA contains lead but provided no data to support this assertion. Petitioners also assert that the use of HFSA in lead-containing water piping systems results in leaching of lead from lead-containing water piping systems into water (Ref. 5), and that when chloramine is used in conjunction with silicofluorides greatly enhanced leaching of lead into water occurs (Ref. 3). However, multiple other studies concluded that the fluoridation of drinking water with HFSA has little impact on corrosivity and/or release of metals from plumbing materials (Refs. 10, 11, 12, and 13). For example, the Centers for Disease Control and Prevention (CDC) conducted a study of the relationship between the additives used for fluoridation (i.e.,

HFSA, sodium silicofluoride, and sodium fluoride) and blood lead concentrations among a nationally representative sample of >9,000 U.S. children, aged 1-16 years (Ref. 10). The study analysis did not offer support for the hypothesis that silicofluorides in community water systems increase blood lead concentrations in children. Based on the available evidence, EPA cannot conclude that the use of HFSA, with or without the presence of chloramine, results in enhanced leaching of lead.

Further, and as discussed in this unit, as petitioners seeking that EPA initiate a TSCA section 6 rulemaking banning HFSA pursuant to TSCA section 21, petitioners must provide facts that establish it is necessary to issue a TSCA section 6 rulemaking, including that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture (in this case HFSA), or that any combination of those activities, presents or will present an unreasonable risk of injury to health or the environment. Here, petitioners have not provided information specific to the costs and benefits of using pharmaceutical grade NaF as compared to HFSA with respect to lead. In sum, with respect to concerns about lead, petitioners have not demonstrated that the use of HFSA presents or will present an unreasonable risk of injury to health or the environment or that it is necessary to initiate a TSCA section 6(a) rulemaking to protect adequately against such risk.

3. TSCA section 9(b). TSCA section 9(b) directs EPA to take regulatory action on a chemical substance or mixture under other statutes administered by the Agency if the EPA Administrator determines that actions under those statutes could eliminate or reduce to a sufficient extent the risks posed by the chemical substance or mixture. If that is the case, the regulation can be promulgated under TSCA only if EPA determines that it is in

the "public interest" to protect against that risk under TSCA rather than the alternative authority. 15 U.S.C. 2608(b).

In 1974, Congress passed the Safe Drinking Water Act (SDWA). That law requires EPA to determine the level of contaminants in drinking water at which no adverse health effects are likely to occur with an adequate margin of safety. These non-enforceable health goals, based solely on possible health risks, are called maximum contaminant level goals (MCLG). The MCLGs for both arsenic and lead are zero. EPA has set these levels based on the best available science, which indicates there is no safe level of exposure to arsenic or lead. However, for most contaminants, EPA sets an enforceable regulation called a maximum contaminant level (MCL) based on the MCLG. The MCLs are set as close to the MCLGs as possible, considering cost, benefits, and the ability of public water systems to detect and remove contaminants using suitable treatment technologies.

In 2001, EPA amended the arsenic standard for drinking water, lowering it to 0.010 parts per million (ppm) (10 ppb) to protect consumers served by public water systems from the effects of long-term, chronic exposure to arsenic (Ref. 16). As part of that rulemaking, EPA performed an extensive review – including review by EPA's Science Advisory Board – of both the costs and benefits to determine what the appropriate achievable MCL should be. The MCL established by EPA was one that maximizes health risk reduction benefits at a cost that is justified by the benefits. 42 U.S.C. 300g-1(b)(6)(A). As a result, EPA has already weighed costs, benefits, and risk reduction relating to arsenic in drinking water as part of its rulemaking efforts under SDWA. The petition provides no information that would cause EPA to question the

conclusions reached in that rulemaking. That rulemaking, as with other drinking water standards under SDWA, is reviewed every 6 years to determine whether revisions are appropriate. 42 U.S.C. 300(g)-1(b)(9). EPA believes, therefore, that the SDWA standard-setting process provides the most appropriate regulatory authority to eliminate or reduce to a sufficient extent the health risks from arsenic in drinking water systems.

While arsenic levels in HFSA are higher than in pharmaceutical grade NaF, the arsenic levels in drinking water due to HFSA use presented in the cost-benefit analysis submitted by petitioners (at 0.078 ppb and 0.00084 ppb respectively (Ref. 2)), are lower than the arsenic MCL of 10 ppb. In addition, these levels are also lower than the NSF International/American National Standards Institute Standard 60-2012 Drinking Water Treatment Chemicals - Health Effects (NSF/ANSI 60-2012) for drinking water treatment chemicals (i.e., single product allowable concentration (SPAC)) of 1 ppb (Refs. 14 and 15). When the Agency established the arsenic MCL in 2001, the Agency noted that the lung and bladder cancer risks at the 10 ppb level were within the Agency's target risk range of 10⁻⁴ to 10⁻⁶ (Ref. 16). Therefore, the excess cancer risk attributable to HFSA at the 0.078 ppb arsenic concentration (128 times lower than the arsenic 10 ppb MCL) would be consistent with the Agency's acceptable excess lifetime cancer risk range of 10⁻⁴ to 10⁻⁶.

NSF compiled data from initial and annual monitoring tests for fluoridation products that NSF certified to NSF/ANSI 60 between 2007 and 2011 (216 samples) and between 2000 and 2006 (245 samples). Arsenic was detected in 50% of the 216 samples analyzed between 2007 and 2011. The mean arsenic concentration was 0.15 ppb (non-detects were estimated at ½ the detection limit) and the maximum was 0.6 ppb. Arsenic

was detected in 43% of the 245 samples analyzed between 2000 and 2006. The mean arsenic concentration was 0.12 ppb (non-detects were estimated at ½ the detection limit) and the maximum was 0.6 ppb. In both sets of data, the mean and the maximum values were less than the NSF/ANSI 60 SPAC of 1 ppb (Ref. 15). Fluoridation additive dosing was at the highest optimal level (i.e., 1.2 mg/L of fluoride). At the newly proposed optimal fluoride dosing of 0.7 mg/L (Ref. 17), the concentration of arsenic would be approximately 40% lower.

To address lead in drinking water, EPA promulgated the Lead and Copper Rule under SDWA in 1991 (Ref. 11) and revised the regulation in 2000 and 2007 (see 40 CFR parts 141 and 142). The rule is undergoing a longer-term revision at this time. Because lead contamination of drinking water often results from corrosion of the plumbing materials in the distribution system, EPA established a treatment technique, rather than an MCL, for lead. A treatment technique is an enforceable procedure or level of technological performance that water systems must follow to ensure control of a contaminant. The regulation requires systems to collect tap samples from sites served by the system that are more likely to have plumbing materials containing lead. If more than 10% of tap water samples exceed the lead action level of 15 ppb, then water systems are required to take additional actions to control the corrosivity of the water including:

- Taking further steps to optimize their corrosion control treatment (for water systems serving 50,000 people that have not fully optimized their corrosion control).
- Educating the public about lead in drinking water and actions consumers can take to reduce their exposure to lead.
 - Replacing the portions of lead service lines (lines that connect distribution mains

to customers) under the water system's control.

In sum, EPA's Lead and Copper Rule under SDWA already directly addresses lead leaching in drinking water distribution systems and the rule is subjected to periodic review and revision to incorporate the latest scientific studies. Like the arsenic rule under SDWA, EPA's requirements under SDWA related to lead in drinking water distribution systems already address and balance risks, costs, and benefits, and, as with arsenic, the petition provides no information that would cause EPA to question the current approach. EPA believes, therefore, that the SDWA provides the most appropriate authority (and in fact has been used) to eliminate or reduce to a sufficient extent the health risks identified by petitioners as being associated with HFSA when used as a fluoridation agent.

4. Radionuclides. Although the petitioners mention "concern" about radionuclides, the petitioners present limited information to support a claim that HFSA presents or will present and unreasonable risk with respect to radionuclides. NSF compiled data from initial and annual monitoring tests for fluoridation products that NSF certified to NSF/ANSI 60 between 2007 and 2011 (216 samples) and between 2000 and 2006 (245 samples). Alpha emitters (type of radioactive decay in which an atomic nucleus emits an alpha particle) were detected in less than 1% of the 216 samples analyzed between 2007 and 2011. The mean (non-detects were estimated at ½ the detection limit) and maximum values were less than the MCL of 15 picoCuries per liter (pCi/L) and were less than the NSF/ANSI 60 SPAC of 1.5 pCi/L (Ref. 15). Beta photon emitters (another type of radioactive decay in which an atomic nucleus emits a beta particle) also were detected in less than 1% of the 216 samples analyzed between 2007 and 2011. The mean (non-detects were estimated at ½ the detection limit) and maximum

values were less than the MCL of 4 millirems per year (mrem/y) and were less than the NSF/ANSI 60 SPAC of 0.4 mrem/y (Ref. 15). Radionuclides (alpha or beta) were not detected in any (0%) of the 245 samples analyzed between 2000 and 2006 (Ref. 11). The concentrations reported represent contaminant levels expected when the fluoridation products are dosed into water at the allowable maximum use levels for NSF/ANSI 60-2012 (see Refs. 14 and 15). NSF notes that lower product use levels would produce proportionately lower contaminant concentrations.

Thus, the petition has failed to present facts that establish that HFSA presents or will present an unreasonable risk of injury to health or the environment with respect to radionuclides, or that it is necessary to issue a TSCA section 6 rulemaking to protect health and the environment from such risk.

For the reasons set forth in this document, EPA denied the TSCA section 21 petition.

V. References

INFORMATION CONTACT.

As indicated under **ADDRESSES**, a docket has been established for this document under docket ID number EPA-HQ-OPPT-2013-0443. The following is a listing of the documents that are specifically referenced in this action. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER**

1. American University students, alumni, and faculty. Letter from J. William

Hirzy to EPA Acting Administrator Robert Perciasepe, "Re: Citizen Petition Under Toxic Substances Control Act Regarding the Hydrofluorosilicic Acid (HFSA) in Drinking Water." May 9, 2013.

- 2. Hirzy, J.W.; Carton, R.J.; Bonanni, C.D.; Montanero, C.M.; and Nagle, M.F. Comparison of hydrofluorosilicic acid and pharmaceutical sodium fluoride as fluoridating agents—a cost–benefit analysis. *Environmental Science & Policy*. Vol. 29, pp. 81-86. 2013.
- 3. Maas, R.P.; Patch, S.C.; Christian, A-M.; and Coplan, M.J. Effects of fluoridation and disinfection agent combinations on lead leaching from leaded-brass part. *Neurotoxicology*. Vol. 28, pp. 1023-1031. 2007.
- 4. Coplan, M.J.; Patch, S.C., Masters, R.D; and Bachman, M.S. Confirmation of and explanations for elevated blood lead and other disorders in children exposed to water disinfection and fluoridation chemicals. *Neurotoxicology*. Vol. 28, pp. 1032-1042. 2007.
- 5. Edwards, M.; Triantafyllidou, S.; and Best, D. Elevated blood lead in young children due to contaminated drinking water: Washington, DC 2001-2004. *Environmental Science & Technology*. Vol. 43, pp. 1618-1623. 2007.
- 6. Masters, R.D. and Coplan, M.J. Water treatment with silicofluorides and lead toxicity. *International Journal of Environmental Studies*. Vol. 56, pp. 435-449. 1999.
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- 8. Stein, M.; Starinsky, A.; and Kolodny, Y. Behaviour of uranium during phosphate ore calcination. *Journal of Chemical Technology and Biotechnology*. Vol. 32,

- pp. 834-847. 1982.
- 9. EPA. EPA Correction of the "Comparison of hydrofluorosilicic acid and pharmaceutical sodium fluoride as fluoridating agents—a cost–benefit analysis" by Hirzy et al. 2013.
- 10. Macek, M.D.; Matte, T.D.; Sinks, T.; and Malvitz, D.M. Blood lead concentrations in children and method of water fluoridation in the United States, 1988-1994. *Environmental Health Perspectives*. Vol. 114, pp. 130-134. 2006.
- 11. EPA. Drinking Water Regulations, Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper; Final Rule. **Federal Register** (56 FR 26460, June 7, 1991).
- 12. American Water Works Association (AWWA). Water Fluoridation Principles and Practices. *AWWA Manual M4*. Fifth Ed. Denver: AWWA. 2004.
- 13. Urbansky, E.T. and Schock, M. R. Can fluoridation affect lead (II) in potable water? Hexafluorosilicate and fluoride equilibria in aqueous solution. *International Journal Environmental Studies*. Vol. 57, pp. 597-637.
- 14. NSF International. June 7, 2013. Available at http://www.nsf.org/business/standards_and_publications.
- 15. NSF International. NSF Fact Sheet on Fluoridation Products. June 7, 2013.Available at
- http://www.nsf.org/business/water_distribution/pdf/NSF_Fact_Sheet_flouride.pdf.
- 16. EPA. National Primary Drinking Water Regulation; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring; Final Rule.
 Federal Register (66 FR 6976, January 22, 2001).

17. Health and Human Services Department (HHS). Proposed HHS
Recommendation for Fluoride Concentration in Drinking Water for Prevention of Dental
Caries; Notice. **Federal Register** (76 FR 2383, January 13, 2011).

List of Subjects in 40 CFR Chapter I

Environmental protection, Hydrofluorosilicic acid (HFSA), Drinking water, Toxic Substances Control Act (TSCA).

Dated: August 6, 2013.

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Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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